REMARKS

Claim 15 has been amended to delete a limitation from the claim and new claim 42, dependent on claim 15, has been added based on this deleted limitation. Upon entry of this amendment, claims 15-30 and 42 will be pending in the present application.

I. Claim Amendments

Claim 15 has been amended to delete a limitation from the claim. New claim 42 dependent on claim 15 has been added based on the limitation deleted from claim 15.

Claim 15 has also been amended to clarify that one of the shank-like element and the head moves relative to the other of the shank-like element and the head to cause the arms to move from the first position to the second position. It is considered that this second amendment to claim 15 does not alter the scope of the claim.

II. The Rejection Under 35 U.S.C. 103(a)

Claims 15-30 have been rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent no. 5,699,918 (Balazs). This rejection is traversed and reconsideration is requested for the reasons which follow.

The feature of claim 15 that the Examiner acknowledged was not present in Balazs has been deleted from claim 15 and thus the applicant does not intend to rely on that feature in support of the patentability of claim 15.

The applicator of the present claims 15-30 and 42 is adapted for anastomosis via two distinct actions which are carried out sequentially:

1. Tissue presentation which is done by expansion of the applicator and movement of the arms from a first position to a second position, and

2. Tissue bonding which is done by permanently deforming the joining elements.

This two-step sequence has proven, in practice, to be extremely important since proper tissue presentation by device and arm expansion, to position the vessel walls around the applicator, positions the vessel walls for deployment of the joining elements to make the connection. This method minimizes errors in tissue capture by the joining elements (e.g. missing a part of the vessel wall – See page 13, lines 25-28 of the specification) thereby greatly enhancing the reliability of the anastomosis.

A basic objective of anastomosis construction is the creation of a wide open connection between two hollow structures wherein the connection between the two hollow structures has an unobstructed smooth inner geometry. To realize this goal, the widely used prior art method precisely places sutures very near to the ends or edges of the severed hollow structures. Such a procedure is discussed, for example, in the background of the Balazs reference cited by the Examiner. See e.g. col. 1 of Balazs). Balazs desires to modify the known method so that it can be performed by minimally invasive surgery (MIS). However, Balazs' method has some disadvantages relative to the widely used prior art method which precisely places the sutures very near to the edges of the severed hollow structures.

In the prior method, all of the available wall material of the hollow structures joined by the anastomosis can contribute to creating the roomiest possible inner geometry of the resultant joined hollow structure. This is because the sutures are located very near to the ends or edges of the severed hollow structures that are to be joined and thus very little wall material is sacrificed to make the anastomosis. This is not the case in Balazs. Specifically, Balazs must sacrifice a significant amount of the wall material at the ends or edges of a severed hollow structure in order to prepare the hollow structure for making an anastomotic connection. This is because Balazs relies on pinching the wall material of the hollow structure between the hooklike shoulders 23 of gripper and holder arms 20 and the mandrel or plunger 5 for positioning the wall material of the hollow structure for insertion of staples and purse string sutures. See e.g. col. 8, lines 28-31 of Balazs. As a result, Balazs must cut off excess protruding wall material using circular-linear blade 41 of annular knife 4 once the staples and purse string sutures have been placed. See e.g. col. 8, lines 34-42 of Balazs.

Minimizing the amount of wasted wall material that extends beyond the desired location of the anastomotic connection is highly advantageous especially because it greatly facilitates the making of end-to-side and side-to-side anastomoses, which are the types of anastomoses most commonly used for connecting blood vessels. Having to cut away a piece of the wall material in a process for making an anastomotic connection to a side of a vessel would inevitably reduce the circumference of the connected hollow blood vessel. The circumference of the connected hollow blood vessel is very important since the smaller the circumference of the vessel, the greater the likelihood that a subsequent obstruction of the connected vessel will result. This concept is reflected in the standard technique for connecting for blood vessels, as for example suturing bypass grafts to coronary arteries (see for example the description in Edmunds, Norwood, low., *Atlas of Cardiothoracic Surgery,* p. 60-61. Lea & Febinger (LWW), Philadelphia, PA, USA, 1990).

The precise placement of the sutures using the prior art method is time consuming and requires considerable skill as well as unhindered access to the hollow structures which makes this procedure unsuitable for minimally invasive surgery, as noted by Balazs. This also explains why surgeons need a long period of training, and why standard techniques are generally not suitable for minimally invasive surgical or endoscopic applications.

The substantial difficulty of precisely positioning the joining elements relative to the vessel wall ends or edges is solved by the device of the present invention by first expanding the device while located inside holes in the walls of the adjacent hollow structures, and only then creating the vessel wall bond by deforming the joining elements. This specific sequence of movements, in combination with the claimed features of the device, position the joining elements close to the ends or edges of the tissue. This requires the joining elements to be held by the pivoting arms, which accomplish the expansion of the vessel walls in order to be achieved.

Balazs discloses an instrument to facilitate the attachment of staples and purse string sutures to the severed ends of hollow structures, in particular bowels. The fundamentally different concept behind this device is reflected by two crucial differences:

- The plurality of arms (ref. 20, Fig 2a) is designed to pivot into the direction of center axis A of the instrument, upon retraction of mandrel 5 (ref. 20, Fig. 2b; column 8, lines 21-27). This motion creates waste material at the end of the hollow vessel since it results in placement of the staples 32 at a distance from the end of the hollow structure. Subsequently, the staples (ref. 32, Fig. 2a) are placed at a distance from the severed end of the hollow structure and deformed. To locate the staples near the severed end of the hollow structure (bowel in this case), excess bowel material is removed by a circular knife (ref. 41, Fig. 2a; column 8, lines 28-42).
- Attaching the joining elements (staples, ref. 32, Fig 2a) to form an anastomotic connection between two hollow structures is nowhere described in Balazs, and is not obvious due to the different joining concept. Note that the Balazs description ends with an indication that, "In this way, by means of the surgical instrument of the invention, a purse string suture is applied to one bowel end, and the bowel end is prepared for receiving a Valtrac® or bioabsorbent anastomosis ring." Col. 8, lines 47-51 of Balazs. Thus, Balazs does not actually describe the step of joining two hollow structures together but instead only describes a device and method for preparing an end of a hollow structure for a subsequent anastomosis step.

These features of the Balazs device prevent the device described by Balazs from being suitable for side-to-side and end-to-side anastomoses and illustrate the substantial differences between the present invention and the device of Balazs.

Referring now specifically to the claim language, the device of Balazs clearly lacks the following features of claim 15 of the present application:

(1) a head provided with a plurality of arms,

(2) movement of one of said shank-like element and said head relative to the other of said shank-like element and said head, causing said arms to move from said first position toward said second position, and

(3) wherein the distal ends of the arms hold said joining elements while positioning at least one said hollow structure relative to said joining elements for making an anastomosis between the hollow structures.

With respect to element (1), the head 1 of the Balazs device is not provided with arms. The arms 20 of the Balazs device are attached to a holder part 2 instead of the head 1. It would not be obvious to attach the arms 20 of the Balazs device to the head 1 of the Balazs device since the arms 20 would then no longer be able to accomplish their intended functions.

With respect to element (2), the examiner takes the position that the mandrel or plunger 5 of Balazs is the shank-like element of claim 15 of the present application. In the device of Balazs the head 1 and mandrel or plunger 5 move together as shown in Figs. 2a-2b and thus do not move relative to one another, as is required by claim 15. Accordingly, there is no disclosure of the possibility of relative movement between the head 1 and the mandrel or plunger 5 of Balazs, as required by the present claims.

With respect to element (3), the staples 32 of Balazs are held in the staple holder 30 which is not part of the arms 20. Thus, the joining elements (staples 32) of Balazs are not held by the distal ends of the arms while positioning at least one hollow structure for anastomosis as is required by claim 15.

The claimed combination of elements (1)-(3) above is used in the device of the present invention to position both the hollow structures and the joining elements for anastomosis. This combination of features positions the joining elements at the ends or edges of the hollow structure by bringing the joining elements to the ends or edges of the vessel wall as a result of movement of the device from the first to the second position thereby avoiding the problem of Balazs that a portion of the wall material of the hollow structure must be cut off and discarded. Also, the present invention is

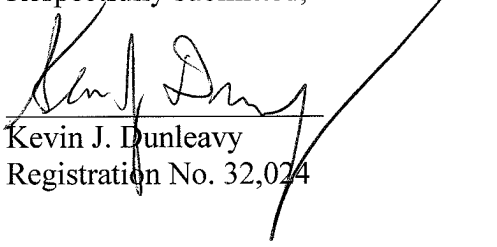
suitable for end-to-side and side-to-side anastomosis since the joining means can be positioned close to the edge of the hole in the side of the vessel without wasting wall material and thereby constricting the circumference of the connected hollow vessel.

The Examiner has presented no evidence in support of a teaching, suggestion or motivation for a skilled person to make the modifications that would be necessary to arrive at the device of the present claims starting from the device of Balazs. For example, the secondary reference to Filipi, U.S. Patent no. 4,505,414 discloses an expandable anvil provided with anvil struts or arms 33 (Fig. 2 of Filipi). However, the anvil struts or arms 33 of Filipi also do not support the joining elements during positioning of the hollow structures and thus the joining elements cannot be brought to the ends or edges of the hollow structures by the anvil struts or arms of Filipi either. As a consequence, Filipi also does not solve the problem of Balazs that a portion of wall material must be wasted to make the connection.

Accordingly, for the foregoing reasons, the device of the present invention is considered to be clearly unobvious over Balazs. Favorable consideration and withdrawal of the rejection is requested.

Issuance of a Notice of Allowance is requested.

Respectfully submitted,



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